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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/915,615	07/26/2001	Marta Gomez-Chiarri	5408	6818
7590 09/16/2004				
Attn: Richard L. Stevens Samuels, Gauthier & Stevens LLP Suite 3300 225 Franklin Street Boston, MA 02110			EXAMINER LAMBERTSON, DAVID A	
			ART UNIT 1636	PAPER NUMBER

DATE MAILED: 09/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/915,615

Applicant(s)

GOMEZ-CHIARRI ET AL.

Examiner

David A. Lambertson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 7 and 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 9-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I (claims 1-6) in the reply filed on July 12, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-17 are pending in the instant application. Upon further consideration, the Office has decided to rejoin claims 9-17 with the elected invention of Group I. As such, claims 1-6 and 9-17 are under examination in the instant application. Claims 7 and 8 remain withdrawn as being drawn to a non-elected invention.

Priority

If applicant desires priority under 35 U.S.C. § 119(e) based upon a previously filed application, specific reference to the earlier filed application must be made in the instant application. For benefit claims under 35 U.S.C. §§ 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. ____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

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If the application is a utility or plant application filed under 35 U.S.C. § 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. § 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. § 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR § 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. § 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. §§ 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. §§ 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. §§ 120 or 119(e) and 37 CFR § 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR § 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR § 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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Information Disclosure Statement

The information disclosure statement filed January 25, 2002 has been considered, and a signed and initialed copy of the form PTO-1449 is attached to this Office Action.

Specification

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Specifically, page 10, lines 6-7 and page 24, line 12 contain(s) nucleotide sequences that are not identified by SEQ ID NOS, and two of which (those on page 10) are not listed in the sequence listing. It is noted that SEQ ID NO: 1 and 2 as listed in the sequence listing do not correspond with the sequences on page 10. Applicant is required to provide a new sequence listing, both the paper copy and computer readable format (CRF), including all sequences encompassed by the definitions set forth in 37 C.F.R. 1.821(a)(1) and (a)(2). In addition, applicant must provide a statement indicating the paper copy and CRF are the same, and that they do not incorporate new matter into the instant specification. Finally, applicant is required to amend the specification to clearly identify the sequences with their appropriate SEQ ID NO.

In this instance, the nature of the non-compliance with 37 C.F.R. 1.821-1.825 does not preclude the examination of the application on the merits, the results of which are communicated below. However, failure to comply with all of the requirements of 37 C.F.R. 1.821-1.825 in response to this Office Action will be considered non-responsive.

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The disclosure is further objected to because of the following informalities: (a) the specification does not contain a reference to the claimed priority application; (b) the Brief Description of the Drawings does not contain a reference to the panels set forth in Figures 1-4; (c) on page 26, line 4 of the specification, there is a reference to a co-pending US Application, but the application number is absent.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4-6 and 9-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of inducing an immune response in a fish by immersing the fish in a solution comprising transformed, killed *E. coli* or *V. anguillarum*, does not reasonably provide enablement for a method of inducing an immune response in a fish by immersing the fish in a solution comprising any transformed, killed bacterium. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the specification coupled with information known in the art without undue experimentation (*United States v. Telectronics*, 8 USPQ2d 1217 (Fed. Cir. 1988)). Whether undue experimentation is needed is not based upon a single factor but rather is

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a conclusion reached by weighing many factors. These factors were outlined in *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and again in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988), and the most relevant factors are indicated below:

Nature of the invention. The nature of the invention is a method of inducing an immune response in a fish through the transfer of a DNA vaccine (carried on a vector/plasmid) into a target fish organism via a killed bacterial cell. In order to practice the invention, the skilled artisan requires: (a) a bacterial cell that is invasive for fish, such that the DNA vector can be transferred into the fish and the immune response induced; (b) a plasmid DNA sequence that is capable of replicating in the bacterial cell, and which can express the antigenic protein in the target fish upon its transfer.

Breadth of the claims. The claims are broad in terms of the bacterial cell that can be used to induce the antigenic response in a fish cell. This is because the types of bacteria that are both (a) invasive to fish and (b) can be transformed with an appropriate DNA vector (as set forth above) are narrower in scope than any possible bacteria, as set forth in the claims.

State of the art. At the time of filing, many techniques for inducing an immune response in fish were known in the art; these include direct injection of naked DNA into a target fish, immersion of the target fish in a solution of naked plasmid DNA (i.e., not in a bacterial cell), and introduction of purified antigenic protein to the target fish. The state of the art as it generally regards bacterial transfer of a DNA vector to a target cells indicates that a particular limiting aspect is the ability of the bacteria to invade the target cell (see for example Grillot-Courvalin *et al.*, *Nat. Biotech.* **16**:862-866, 1998; see entire document, especially the Abstract). However, the state of the art at the time of filing was silent as to which fish-invasive bacteria could be used to

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transfer a particular DNA vector to a fish, such that an immune response is induced. Thus, the skilled artisan would need to consult the instant specification as to which invasive bacteria could successfully transfer a particular DNA vector to a fish, and what vectors could be used to acquire the invasive bacteria to be used therein.

Number of working examples and Guidance provided by applicant. The instant specification provides working examples regarding two distinct bacteria that are both invasive to fish and which can carry DNA vectors capable of replicating in the bacterial cells and expressing the antigenic protein, thereby inducing an immune response in the target fish. These two bacteria are *E. coli* and *V. anguillarum*. There is little guidance as to what additional bacteria would be both invasive to fish and which could replicate and transfer a DNA vector that would produce an antigenic protein in a fish cell. Thus, it is unclear how the skilled artisan would use bacteria other than *E. coli* and *V. anguillarum* to use the claimed invention.

Unpredictability of the art and Amount of experimentation required. The invention as claimed would require an undue amount of unpredictable trial and error experimentation in order to use the method across its full scope. While the skilled artisan would understand the vectors that could be used in *E. coli* and *V. anguillarum*, the skilled artisan would need to empirically determine (a) what other bacteria would have an invasive characteristic towards fish, such that a DNA vector could be transferred therein and (b) what vectors could be used in these bacterium to successfully cause the expression of an antigenic protein in the target fish. Because it is not immediately clear from either the instant specification or the prior art as to which bacteria and respective vectors will have this invasive and immune inducing capacity, the skilled artisan could not use the invention across its broadly claimed scope.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 and 9-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 9 (and their depending claims) are rejected under 35 USC 112, second paragraph, as being indefinite for failing to recite a positive process step that refers back to the preamble of the claim. In order for the claimed method to be definite in terms of the metes and bounds of the invention, the claim must recite a method step that provides for the result of the methods as claimed. Specifically, claims 1 and 9 are directed to a method of inducing an immune response in a fish, but there is no positive process step indicating that an immune response has been produced in a fish. In the absence of such a step, it is unclear if the method has been performed to completion. Because the end of the claimed method is unclear, the metes and bounds of the claim are not defined.

Claims 2, 10 and 13 are rejected for the recitation of the phrase "group of finfish." The term "finfish" on its own is singular, and cannot be considered a group. It would appear the term "finfish" is meant to encompass a selection of fish that falls within the metes and bounds of the term "finfish." However, the selection is not clearly set forth in the claim, therefore the nature of the group to be selected from is indefinite. It is noted that on page 3 of the instant specification, a list of examples of finfish is provided. However, these are only examples, and exemplification

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does not define the metes and bounds of a term. It is recommended that when amending the instant claim, the full definition of what is meant by “finfish” is set forth.

Claims 4 and 12 are rejected under 35 USC 112, second paragraph, as being indefinite for failing to recite a proper Markush group. In order for the claims to be definite, they must recite the proper Markush language, wherein the members of the Markush group are “selected from the group consisting of”, followed by the listing of the members of the group. In addition, the conjunction “and” must follow the penultimate member of the group. Specifically, in the instant claims it is unclear if both *omp48* and *omp38* must be selected, or if either one can be selected; this is because the group that is to be selected from only includes a choice of both *omp48* and *omp38* as a member of the group (as opposed to either of them). This is also true when selecting from IHNV and VHSV proteins.

Claim 5 recites the limitation “the plasmid” in reference to claim 4 (and ultimately claim 1). There is insufficient antecedent basis for this limitation in the claim; it is noted that claim 1 recites a “vector,” which is not identical in scope to a “plasmid.”

Claim 5 is rejected for lacking a period at the end of the claim. As such, it is unclear if there are additional limitations to the claim, or if there is a punctuation error.

Claim 11 (and its depending claims) is rejected under 35 USC 112, second paragraph, as being indefinite for failing to recite a positive process step that refers back to the preamble of the claim. In order for the claimed method to be definite in terms of the metes and bounds of the invention, the claim must recite a method step that provides for the result of the methods as claimed. Specifically, claim 11 is directed to a method of introducing DNA to a fish, but there is no positive process step indicating that the DNA has been introduced in a fish. In the absence of

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such a step, it is unclear if the method has been performed to completion. Because the end of the claimed method is unclear, the metes and bounds of the claim are not defined.

Claim 16 is rejected under 35 USC 112 for recitation of the term AFP. It is unclear what this acronym means in the absence of a "spelling out" of the terms within the acronym.

Allowable Subject Matter


No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (571) 272-0771. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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JAMES KETTER
PRIMARY EXAMINER